EPO
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## Peer Review of Research

On October 1, 2002, CDC implemented a new policy on external peer review of extramural and intramural research, and research contracts. The Extramural Research Working Group, which was charged to make recommendations for central support and standardization of processes and procedures for extramural research at CDC/ATSDR, recently released their report on the new policy at the Excellence in Science meeting.

### Extramural Research

The policy requires that all extramural research awarded or conducted by CDC on or after October 1, 2005 (FY 2006) must be peer reviewed except in emergency situations. This policy applies to

- Research funded by grants or cooperative agreements;
- Research as a component of a non-research announcement. If any research projects are part of the announcement, all components of the proposal should be peer reviewed.
- Institutional awards to research centers to support centralized resources and facilities shared by investigators conducting research.

### Intramural Research Programs

The policy requires all Centers, Institutes, and Offices (CIOs) to initiate peer review of intramural research programs by a

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## Inside this Issue



## A Summary of the Department of Health and Human Services (DHHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public

In October 2002, the U.S. Department of Health and Human Services (HHS) released Guidelines for Ensuring the Quality of Information Disseminated to the Public. The purpose of this document to ensure that data released from CDC are of the highest quality, and to outline a procedure for public complaint if the public believes that any data released to the public are incorrect and people have been been harmed as a result. The guidelines described here do not apply to the National Center for Health Statistics (NCHS), which has separate guidelines.

The HHS Guidelines for Ensuring the Quality of Information Disseminated to the Public (i.e., the Guidelines) are available at http://www.hhs.gov/infoquality/cdcinfo2.htm. The crux of the document is that Associate Directors for Science (ADS) will have responsibility for enforcing CIOs' compliance with the guidelines; most of the provisions of the Guidelines are consistent with existing procedures at CDC.

The Guidelines apply only to information disseminated on or after October 1, 2002, and apply to information in all media–print, electronic, audiovisual, and oral; substantive information, such as studies and reports, but not information pertaining to basic agency operations; and information that is disseminated at the request of CDC or with specific CDC approval through a contract, a grant, or a cooperative agreement.

Examples of the types of information that CDC considers within the scope of the

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## Research and the Privacy Rule (Q&A)

The *Health Insurance Portability and Accountability Act of 1996 Privacy Rule (HIPAA Privacy Rule)* establishes conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes. The Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research. See Office of Civil Rights guidance on privacy rule http://www.dhhs.gov/ocr/hipaa/whatsnew.html.

Following are answers to some of the most frequently asked questions regarding research and the Privacy Rule.

### What does the Privacy Rule cover?

The Privacy Rule covers one type of data–protected health information (PHI). PHI is health information that directly identifies the person who is the subject of the information or contains data for which there is reason to believe that the information can be used to identify the individual. Health information that has been de-identified is not protected by the Privacy Rule.

### What does the Privacy Rule regulate?

Because the authority for the Privacy Rule comes from HIPAA legislation, the Rule regulates conditions for using PHI that is created, maintained, or transmitted by certain health care providers, health plans, and health care clearinghouses. These groups are collectively called covered entities. *The Rule does not regulate other forms of health information, including information obtained directly from individuals or from other entities.*

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## Ethical Dilemmas in Public Health

**Scenario 1** A research participant wants to withdraw from a study and requests that all information related to him be destroyed, including the consent form and data already collected.

How should the investigator respond to the participant's request?

*The investigator must honor the participant's request to withdraw from the study. However, although the participant has the right to withdraw,the particpant should be informed that the data already collected would be destroyed only if permitted by local,state, or federal law.*

**Scenario 2** In a study, specimens were collected for future testing. The investigator decides that a possible database that could be linked back to study participants is necessary because of the nature of the particular disease of concern.

What important information must the investigator tell the participants in the informed consent letter?

*The investigator should inform the participants that they have the right to refuse to have their specimens stored. The participants should also be told of the type(s) of test expected to be performed and their right to refuse to have a specific test done. No other testing should be done unless specified ir the consent form. If genetic testing is to be done, the participant should be asked for permission to conduct genetic testing on the specimens.*

How should the investigator proceed if a participant later wants to withdraw a specimen from storage and future testing?

*The investigator must stop all testing being performed on the specimen. If destruction of specimens is permitted, it must be done appropriately according to approved guidelines.*

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Federal Advisory Committee Act (FACA)-chartered advisory committee or Board of Scientific Counselors, or a special emphasis panel by October 1, 2005 (FY2006).

**Intramural Research Studies**

The policy also requires all CIOs to use external experts to review major studies for scientific and technical quality at least once every 5 years by October 1, 2005. External experts will also be used to review major studies at inception and to review research results from major studies prior to dissemination. Major studies are defined as those with large budget or FTE commitments, or projects likely to produce findings of unusually high importance or interest.

**Research Contracts**

All research contracts with direct costs of $100,000 or greater, awarded on or after October 1, 2005 (FY 2006), will be evaluated by peer review, except in emergency situations.

**Timeline for Implementation**

Peer review of all research projects (extramural, intramural, and research contracts) is to be phased in over 3 years by proportion of total number of new announcements (which includes competing continuations) for awards by a CIO. Note that the denominator includes announcements of which any component is research.

Proportion of total research announcements subject to peer review:

- **1 of 3**, implemented for FY2003
- **2 of 3**, implemented for FY 2004
- **9 of 10**, implemented for FY 2005
- **All** awards, implemented for FY2006 and after

The impact on EPO for FY2003 is minimal. EPO does not have any new research or competing continuation projects that fall under the new policy this year.

For more details please refer to the CDC policy document, *Peer Review of Research* (http://basis1.cdc.gov/BASIS/masompb/P

## Frequently Asked Questions

**1. How do I find out the status of my protocol that is under review by CDC IRB?**

If you have access to the CDC Intranet, you can check on the status of your protocol by logging into the CDC IRB Website at http://inside2.od.cdc.gov/adshsp/source/query.asp. If you do not have access to the Intranet you may contact Aun Lor at 404-639-1488 or alor@cdc.gov.

**2. Where can I find past issues of the EPO ADS Newsletters?**

You can find current and past issues of the ADS Newsletter on the EPO ADS Website at www.cdc.gov/epo/ads/index.htm


## OHRP Update

(December 9, 2002) The Office for Human Research Protections (OHRP) has introduced a process for electronic submission of the Federalwide Assurance (FWA) for new filings only. In the near future, you will also be able to electronically submit registration of your institutional review board (IRB) or independent ethics committee (IEC), as well as update an already approved FWA or a registered IRB/IEC.

Electronic submission of the FWA will expedite processing of the assurance by OHRP. With the electronic submission process, notification of approval occurs by e-mail automatically as soon as OHRP approves your submission. Therefore, OHRP encourages institutions to submit the FWA electronically rather than by mail.

You may access the new electronic submission process for the FWA at: http://ohrp.osophs.dhhs.gov/efile/.

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A decision tree from the Center for Medicare and Medicaid Services provides a framework that is useful for deciding if a provider, health plan, clearinghouse, or program is a covered entity (www.cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport/default.asp.)

**How can protected health information (PHI) be used in research?**

Beginning on April 14, 2003, researchers who enroll subjects in research studies that require access to (or who otherwise seek to obtain) data that includes PHI from covered entities will need to

- obtain a signed authorization of disclosure from each research subject to use his or her PHI or to have it disclosed from the covered entity, or
- receive a waiver of authorization of disclosure from an institutional review board (IRB) or a privacy board, or
- sign a data use agreement with the covered entity and agree to receive a limited data set (a data set with some enhanced detail of certain identifiers).

In each case, the researcher may receive only the "minimal data" necessary to conduct the research. The concepts of limited data set with a data use agreement and the requirement for disclosure of minimal data necessary for research will be discussed further in an upcoming message.

Authorization of disclosure is separate from the informed consent process. Although the authorization can be included in or combined with the informed consent form, there are specific requirements for the content of the authorization which may best be dealt with in a separate form. In addition, the wording of the form may vary somewhat by institution, complicating the consent form review process for multisite studies when authorization is included in the informed consent form. The Office of Human Research Protections has provided an initial opinion that the authorization form itself will not need to be reviewed by the IRB if separate from the informed consent form. The authorization form is required to contain certain specific language and will be reviewed by the covered entity for compliance with the regulations before release of or access to the PHI.

A waiver of authorization of disclosure can be granted by the IRB or a privacy board on the basis of certain criteria established in the Privacy Rule. The waiver of authorization might be appropriate for studies in which a waiver of informed consent is used or is being requested, but the investigator will need to request the waiver of authorization separately from the IRB or privacy board.

In addition, the Privacy Rule allows use of PHI without patient authorization for research on decedents and for "preparatory research," i.e., preliminary work to assess if the data can be used for research purposes, provided that the PHI does not leave the covered entity.

**What constitutes identifiers under the Privacy Rule?**

The following are considered identifiers under the Privacy Rule, and the presence of any of these items in data from a covered entity on the health status of the individual would be sufficient to make it protected health information.

- Names
- All geographic subdivision smaller than a state, including ZIP code and geocodes (except for the initial three digits of the ZIP code under certain circumstances)
- All elements of dates except year for dates directly related to an individual, including birth date, admission date, date of service, date of discharge, date of death; and all ages over 89 years, including all elements of dates including birth year indicative of such age (except that there may be a category of age 90 or older)
- Telephone numbers
- Facsimile numbers
- Electronic mail addresses
- Social Security numbers
- Medical record and prescription numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers, including serial numbers and license plate numbers
- Device identifier and serial numbers
- Web Universal Resource Locaters (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including fingerprints and voiceprints.
- Full face photographic images
- Any other unique identifying numbers, characteristic or code

**What are the implications for research exempt from the *Common Rule*?**

Research involving existing data, such as medical records, where the information is recorded in such a manner that subjects cannot be identified is exempt from the Common Rule (45 CFR 46.101(b)(4)). The standard for identifiability defined in Common Rule is that the identity of the subject may be readily ascertained by the investigator (45 CFR 46.102(f)(2)). However, information such as date of birth or date of hospitalization has not previously been considered as an identifier in the determination of research exempt from the Common Rule. This could give rise to a situation in which research that is otherwise exempt from IRB review may still require review by an IRB or privacy board to determine if a waiver of authorization of disclosure is appropriate.

To avoid this situation, studies requesting a determination of exemption to use existing PHI from covered entities should attempt to comply with the Privacy Rule definition of identifiers.

More details about the Privacy Rule and its implications on research are available on the Office of Civil Rights website at http://www.dhhs.gov/ocr/hipaa/whatsnew.html or contact John Livengood (Jlivengood@cdc.gov,) Deputy ADS, CDC.

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guidelines:

- Scientific research papers, books, journal articles, reports, and similar materials, unless they have disclaimers to distinguish the research from CDC views and positions;
- Other official reports, brochures, documents, newsletters, and audiovisual products;
- Oral information, including speeches, interviews, expert opinions only if representing CDC's views, official positions, or policies;
- Statistical information – statistical analyses, aggregated information by programs.

Examples of the types of information that CDC considers outside the scope of the guidelines:

- Documents not authored by CDC (either directly or by contract) and not representing official views, including research and science supported by CDC funding;
- Opinions of which the presentation makes it clear that what is being offered is personal opinion rather than fact or CDC's views;
- Archival information disseminated by CDC (e.g., Internet distribution of published articles);
- Information dissemination limited to government employees or agency contractors or grantees;
- Information intended solely for intra- or interagency use or sharing of government information, such as evaluation of a specific public health program to assess its success in achieving its objectives, technical assistance reports, training materials, manuals;
- Information intended to be limited to public filings, subpoenas, or adjudicative processes;
- Press releases that support the announcement or give public notice of information that CDC has disseminated elsewhere.

CDC reviews the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step in the development of information, including its creation, collection, maintenance and dissemination. The individual CIO ADSs or designees are responsible for assuring the quality of information disseminated by CDC and that the quality assurance methods and procedures described in the Guidelines are met. In addition, the CIO ADS or designee is responsible for clearance and for ensuring that the necessary clearances are obtained and that written material distributed is appropriate and consistent with HHS policy. Although each CIO can determine preparation, review and approval procedures, all must meet the general standards provided by the ADS, CDC, and HHS.

To meet the standards for external merit review of research and scientific studies and intramural research programs, CDC has implemented a policy for peer review of extramural research and intramural research studies and programs (See article on peer review).

The Guidelines call for CDC to developed administrative mechanisms to allow affected persons to seek and obtain correction of disseminated information that does not comply with OMB, DHHS and CDC guidelines. As part of its responsibilities to consumers, CDC will establish a website to inform information consumers of the agency's information quality guidelines, the process for submitting a complaint, information needed by the complainant, and a description of the complaint adjudication process. CDC will centralize the initial receipt, logging, and tracking of all complaints received under this provision in the Management Analysis and Services Office (MASO), Office of Program Services. Complaints will be forwarded to the office that has subject matter responsibility for the information product in question. In the case of the Epidemiology Program Office, MASO will forward the complaint to the OADS, EPO, who will forward the complaint to the appropriate Division for adjudication.

Finally, CDC considers the information disseminated in the MMWR Recommendations and Reports, the Hazardous Substance Release/Health Effects Database, Toxicological Profiles, ATSDR Public Health Assessments, and Federal Register publications related to science as influential scientific information. As such, the Guidelines state that CDC will

- Use the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer-reviewed science and supporting studies when available,
- Use data collected by accepted methods (if reliability of the method and the nature of the decision justifies use of the data).
- Ensure that the presentation of public information about health risks is comprehensive, informative, and understandable, within the context of its intended purpose.

For more information please contact Scott Kellerman at 404-639-0171 or Skellerman@cdc.gov.

**EPO ADS Newsletter**

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